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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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MINTZ, LEVIN, COHN, FERRIS, GLOVSKY
AND POPEO, P.C.
ONE FINANCIAL CENTER
BOSTON, MA 02111

EXAMINER

MYERS, CARLA J

ART UNIT PAPER NUMBER

1634

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/823,197	Applicant(s) CROSSMAN ET AL.	
	Examiner Carla Myers	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-15 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 8-15 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Election/Restrictions

1. Prior to setting forth the restriction requirement, it is pointed out that Applicants have presented claims 8-15 in improper Markush format. See Ex parte Markush, 1925 C.D. 126 and In re Weber, 198 USPQ 334. The claims are improperly joined as the claimed methods require the detection of distinct target molecules. A reference against one target molecule (e.g., a primer to IL-1A +4845) would not be a reference against the other target molecules (a primer to IL-1B -511, IL-1B +3954, IL-1RN (VNTR) or IL-1RN (+2018)). Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because the claims do not recite proper species. Upon election, Applicants are required to amend the claims to set forth only the elected inventive groups.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 8-10 and 12-15, drawn to kits comprising a primer that hybridizes to IL-1A +4845 allele 1, classified in class 536, subclass 24.33.
- II. Claims 8-10 and 12-15, drawn to kits comprising a primer that hybridizes to IL-1B -511 allele 1, classified in class 536, subclass 24.33.
- III. Claims 8-10 and 12-15, drawn to kits comprising a primer that hybridizes to IL-1B +3954 allele 1, classified in class 536, subclass 24.33.
- IV. Claims 8-10 and 12-15, drawn to kits comprising a primer that hybridizes to IL-1RN (VNTR) allele 1, classified in class 536, subclass 24.33.
- V. Claims 8-10 and 12-15, drawn to kits comprising a primer that hybridizes to IL-1RN (+2018) allele 1, classified in class 536, subclass 24.33.

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3. The inventions are distinct, each from the other because of the following reasons:

Inventions I-V are drawn to patentably distinct products, having different structures, physicochemical properties and different functions. The claims encompass primers having different nucleotide sequences and each hybridizing to a different polymorphism. The chemical structure of each polymorphism and of each nucleic acid primer containing the polymorphism is distinct from each of the other polymorphisms and nucleic acids. For example, a primer which hybridizes to IL-1A +4845 allele 1 is chemically, structurally and functionally distinct from a primer which hybridizes to IL-1B-511 allele 1. Further, it is noted that the claims encompass kits containing a combination of primers. The combination of primers is considered to be patentably distinct from the individual primers since again each of the primers differs with respect to their structure and function. Therefore, each of the primers, and combinations thereof, is deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121.

Accordingly, Applicant is required to elect a single primer or a specific combination of primers.

4. These inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their divergent subject matter. Further, these inventions require different database searches that are not co-extensive. For example, a search for a primer which hybridizes to IL-1A +4845 allele 1 would not be co-extensive with a search for a primer which hybridizes to allele 1 of any of IL-1B – 511, IL-1B +3954, IL-1RN (VNTR) or IL-1RN (+2018). Further, a reference which

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anticipates or renders obvious primer which hybridizes to IL-1A +4845 allele 1 would not also necessarily anticipate or render obvious a primer which hybridizes to allele 1 of any of IL-1B -511, IL-1B +3954, IL-1RN (VNTR) or IL-1RN (+2018). Similarly a finding that the primer which hybridizes to IL-1A +4845 allele 2 is novel and unobvious over the prior art would not necessarily extend to a holding that a primer which hybridizes to allele 1 of any of IL-1B -511, IL-1B +3954, IL-1RN (VNTR) or IL-1RN (+2018) are also novel and unobvious over the prior art. Accordingly, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

5. Further, groups I-V are subject to an additional restriction requirement as follows.

Claim 11 is subject to an additional restriction since these claim does not recite a proper genus/Markush group.

Specifically, claim 11 claims distinct primers selected from the group consisting of SEQ ID NO: 1-14. Each of these primers consists of a distinct nucleic acid sequence, has a different melting point, and binds to a different nucleic acid sequence, and thereby has a different biological function. Given the differences in structure and function, the Markush group set forth in claim 11 is not considered to constitute a proper genus, and therefore is subject to a further restriction requirement. A sequence search and non-patent literature search of these sequences would not be co-extensive with one another. For example, a search for the nucleic acid sequence of SEQ ID NO: 1 would not be coextensive with a search of the nucleic acid sequence of SEQ ID NO: 2-14. Further, a reference which renders obvious or non-novel the primer of SEQ ID NO: 1 would not

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also necessarily render obvious or non-novel one of the primers of SEQ ID NO: 2-14.

Similarly, a finding that the primer of SEQ ID NO: 1 is novel and unobvious over the prior art would not necessarily extend to a finding that one of the primers of SEQ ID NO: 2-14 are also novel and unobvious over the prior art. Accordingly, a search of more than one of the primers of claim 11 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and the corresponding examination of more than one of the claimed sequences. Accordingly, Applicants are required to elect one of the primers or one set of the primers selected from the group consisting of SEQ ID NO: 1-14. The elected primer or set of primers should correspond to the elected invention (i.e., one of the inventions of groups I-V, as set forth above). Note that this is not a species election.

Claims 8-10 and 12-15 link the individual primer sequences of claim 11, each sequence comprising a distinct invention as outlined above. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is

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withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.0

6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)-272-0735.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

Carla Myers
September 20, 2006


CARLA J. MYERS
PRIMARY EXAMINER